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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,828	01/25/2006	Hidetsugu Takagaki	060085	7933

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EXAMINER

SIMMONS, CHRIS E

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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01/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,828	Applicant(s) TAKAGAKI ET AL.	
	Examiner Chris E. Simmons	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) 21,23,25,27 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15,17-20,22,24,26,28 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/25/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims: Receipt of the amendment filed on 11/29/2007 is acknowledged. Accordingly, claims 14 and 16 are cancelled (claims 1-13 were previously cancelled). Claim 15 is currently amended. Claims 17-32 are newly added. Claims 15 and 17-32 are presented for examination.

Election/Restrictions

Applicant's election without traverse of Group II (claims 14-16) in the reply filed on 11/29/2007 is acknowledged. Applicant further elected compound 551 shown in Table 15 on page 26 of the present specification.

Claim 21, 23, 25, 27, and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/29/2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 15, 17-20, 22, 24, 26, 28, and 30-32 are rejected under U.S.C. 103(a) as being unpatentable over Kimura et al. (*Chem. Pharm. Bull.* (2001); **49**(10):1321-1325) in view of Postma et al. (*Am J Respir Crit Care Med.* (1998); 158(5 Pt 3):S187-92).

The primary reference discloses TA-270 (i.e., elected compound 551) is useful as an inhibitor of pulmonary inflammatory cell accumulation and airway hypersensitiveness (p. 1321, 1st paragraph, 2nd sentence). The primary reference does

not expressly teach the use of TA-270 in the treatment of chronic obstructive pulmonary disease (COPD).

The secondary reference discloses that lung tissue inflammation, airway obstruction, and airway hyper-responsiveness are important features of COPD (abstract). It discloses chronic bronchitis has been known to have an increase in eosinophils. The secondary reference does not expressly teach the use of TA-270.

The skilled artisan would have found it obvious at the time of the invention to treat COPD with TA-270. The artisan would be motivated by the desire to take advantage of the inhibitory effect of TA-270 on inflammation and airway hypersensitiveness to treat a disease associated with a pulmonary influx of inflammatory cells and airway hyper-responsiveness, especially if there is also airway obstruction involved in the disease. Since, emphysema and chronic bronchitis are sub categories of COPD, one would reasonably expect each to possess the same features as COPD.

Conclusion

No claims are allowed.

The following is pertinent art not relied upon for the current office action:


- Aoki Y., Ishihara M., Koda A., Takagaki H., Eur. J. Pharmacol. (2000); 409:325-330. (Provided in IDS filed 01/25/2006)

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris E. Simmons whose telephone number is (571) 272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Chris Simmons
Patent Examiner
Au 1612

January 28, 2008

Frederick Krass
Supervisory Patent Examiner
AU 1612

